

ONE HUNDRED FIFTEENTH CONGRESS
Congress of the United States
House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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January 30, 2017

The President
The White House
Washington, D.C. 20500

Dear Mr. President:

We write to express our concern regarding the impact the Presidential Memorandum (“the memorandum”) issued on January 23, 2017, implementing an across-the-board hiring freeze, will have on the upcoming reauthorization of the user fee programs at the Food and Drug Administration (FDA).

As you may know, FDA is our preeminent public health agency tasked with the responsibility of overseeing the safety of our food, drugs, medical devices, and cosmetics. FDA-regulated industries account for 20 cents of every dollar spent annually by U.S. consumers. Importantly, FDA plays a key role in supporting innovation here at home. The agency’s drug review program is recognized worldwide as the gold standard, and in recent years FDA has not only approved more new drugs than its European counterparts, but it has also done so more quickly. The work done by FDA and its employees is also critical to protecting the health and safety of our country, work that is now endangered by the recent memorandum released instituting a blanket federal hiring freeze.

The memorandum outlines a federal hiring freeze applying to all federal civilian employees across the executive branch stating: “no vacant positions existing at noon on January 22, 2017, may be filled and no new positions may be created.”¹ Further, the memorandum specifies that the hiring freeze “applies to all executive departments and agencies regardless of the sources of their operational and programmatic funding.”² While exemptions may be permitted if the head of any executive department or agency “deems necessary to meet national

¹ The White House, *Presidential Memorandum Regarding the Hiring Freeze* (January 23, 2017) (www.whitehouse.gov/the-press-office/2017/01/23/presidential-memorandum-regarding-hiring-freeze).

² *Id.*

security or public safety responsibilities”³ or if the Director of the Office of Personnel Management (OPM) determines an exemption is otherwise necessary, it remains unclear whether the important work at FDA would be eligible for such an exemption under this memorandum, and further, how this directive will impact the recent user fee agreements in the areas of drugs, biologics, and medical devices.

Given the uncertainty associated with this presidential memorandum, we respectfully request the answers to the following questions:

1. FDA currently has an estimated 1,000 vacancies at the agency, the majority of which are in the Center for Drug Evaluation and Research. What criteria will the administration use to determine whether or not these vacancies would be eligible for an exemption as outlined in the memorandum? Of the current vacancies at FDA, which vacancies would be subject to the federal hiring freeze outlined in the memorandum and which vacancies may be eligible for an exemption?
2. As you know, FDA recently completed negotiating user fee agreements with the pharmaceutical and medical device industries. Revenues from these user fees are utilized by the agency to meet the performance goals outlined in the agreement, and account for 42 percent of FDA’s funding.⁴ The negotiated performance goals may also include specified hiring goals. For example, the proposed Prescription Drug User Fee Act (PDUFA) VI performance goals includes clear hiring goals for the human drug review program, outlining the hiring of an additional 230 employees over the course of the agreement.⁵ The proposed Medical Device User Fee Amendments (MDUFA) IV performance goals also note that user fee revenues will be used to hire additional review staff.⁶ Is federal hiring utilizing private user fee revenues subject to the hiring freeze outlined in the memorandum? If so, please explain how the agency will be able to meet the negotiated performance goals of the user fee agreements?
3. The 21st Century Cures Act, P.L. 114-255, includes provisions to assist FDA in recruiting and retaining the scientific and technical personnel needed to fulfill the agency’s mission. Is the hiring authority provided to FDA under the 21st Century

³ *Id.*

⁴ Congressional Research Service, *The Food and Drug Administration (FDA) Budget: Fact Sheet* (July 28, 2016).

⁵ Food and Drug Administration, *PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 through 2022* (December 20, 2016) (www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf).

⁶ Food and Drug Administration, *MDUFA Performance Goals and Procedures, Fiscal Years 2018 through 2022* (December 2, 2016) (www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM535548.pdf).

Cures Act subject to the hiring freeze outlined in the memorandum? If so, please explain why.

We urge you to consider carefully how instituting a federal hiring freeze will affect FDA. To that end, we would remind the administration that FDA is tasked with approving novel drugs and medical devices to improve how we prevent and treat medical conditions, as well as approving generic drugs that provide critical competition to the market and affordable access to medications for families. The agency is also responsible for ensuring the food produced in our country is safe to consume, and working with its sister agencies to respond to public health emergencies such as Zika.

The U.S. Government Accountability Office has found that federal hiring freezes are not effective, disrupt agency operations, and can increase costs to the federal government.⁷ Hamstringing the ability of our most critical public health agency to hire the personnel needed will hamper FDA's ability to fulfill its mission and meet the performance metrics, including timelines for medical product reviews and approvals, negotiated with industry under the user fee agreements.

Thank you for your prompt attention to this matter. If you should have any questions regarding this request, please contact Kimberlee Trzeciak of my staff at (202) 225-3641.

Sincerely,



Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce



Gene Green
Ranking Member
Subcommittee on Health



Diana DeGette
Ranking Member
Subcommittee on Oversight
and Investigations

⁷ Comptroller General of the United States, *Recent Government-Wide Hiring Freezes Prove Ineffective in Managing Federal Employment* (March 10, 1982) (www.gao.gov/assets/140/137055.pdf).